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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,549	12/14/2001	Richard Charles Turek	CL/V-31679A	8133

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EXAMINER

PENG, KUO LIANG

ART UNIT PAPER NUMBER

1712

DATE MAILED: 08/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,549

Applicant(s)

TUREK ET AL.

Examiner

Kuo-Liang Peng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/28/03 Amendment.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5-7.
- ☐ Interview Summary (PTO-413) Paper No(s). _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

1. The Applicants' amendment filed on May 28, 2003 was received. Claims 1-2, 5, 9, 20-21, 24, 26 and 28-29 are amended.
2. The text of those sections of Title 35, U.S. code not included in this action can be found in a prior Office Action (Paper No. 4).
3. The indicated allowability of claims 9-22 is withdrawn in view of the indefiniteness issue under 35 U.S.C. 112, second paragraph, nonstatutory double patenting rejection and the newly discovered reference(s) to Covington (US 4 423 195), Hendrickson (US 5 106 533) and Lally (US 6 149 842). Rejections based on the newly cited reference(s) follow.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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5. Claims 2 and 7-8 are directed to an invention not patentably distinct from claims 6 and 7 of commonly assigned copending Application No. 10/153,040. Specifically, Claim 6 of the copending Application is directed to an ophthalmic lens comprising a core polymeric material and an ophthalmically compatible surface wherein said core polymeric material comprises at least a color additive, which reads on the ophthalmic molding of Claim 2 of the instant invention wherein the ophthalmic molding has colored core material, which is surrounded by an ophthalmically compatible surface. Furthermore, Claim 7 of the copending Application is directed to the use of copper phthalocyanine as a color additive in a contact lens, which reads on Claims 7-8 of the instant invention wherein an ophthalmic molding is tinted with a phthalocyanine pigment, more specifically, a copper phthalocyanine blue.

6. The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned copending Application No. 10/153,040, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

7. Claims 2 and 7-8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6 and 7 of copending Application No. 10/153,040. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reason described in paragraph 5.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In Claims 1, 9, 24 and 29, the phrase “high oxygen permeability” causes confusion because it is not clear as how high it is.

Claim Rejections - 35 USC § 102

10. Claims 1-6, 24-26 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Covington (US 4 423 195).

With respect to Claims 1-6, Covington discloses a flexible silicone contact lens prepared by polymerizing of monomer mixture comprising a polysiloxane macromer and an ethylenically unsaturated monomer (col. 2, lines 51-68, col. 3, lines 1-33 and col. 4, lines 56-64). Organic or inorganic pigments such as titanium oxide, etc can be incorporated into the monomer mixture (col. 10, lines 10-22). The oxygen permeability can be from about 29 to 62 (col. 14, lines 67-68). Since Applicants do not specify how high is the “high oxygen permeability”, Covington’s method reads on the method of the instant claim. The surface of the Covington’s contact lens is in contact with an ophthalmic environment (col. 2, lines 64-68). Therefore, it is ophthalmically compatible.

With respect to Claims 24-25 and 29-30, it is noted that the instant claim does not exclude the possibility of the dispersing agent being the same material as component (i). As such, although Covington does not use a pigment dispersion which is prepared as a separate component from the “crosslinkable or polymerizable material”, Covington’s contact lens reads on the soft, tinted ophthalmic lens of the instant claim because the dispersing agent which is crosslinkable or polymerizable with component (i) in the instant claim is eventually incorporated into the final lens matrix (i.e., absence of the pigment dispersion) after polymerization or crosslinking.

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With respect to Claim 26, Convington further teaches the use of a dimethylpolysiloxane macromer (col. 4, lines 65-68).

11. Claims 1-17, 21-26, 27-28 and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lally (US 6 149 842).

With respect to Claims 1-4, 9, 10-11, 14, 23, 24 and 29-30, Lally discloses a soft, tinted ophthalmic molding by a method wherein a water soluble polymer precursor is used, and a pigment is entrapped in the resulting polymeric matrix (col. 2, lines 25-44). The ophthalmic molding has a balance of water content, oxygen permeability and mechanical properties. The ophthalmic molding can be a contact lens (col. 14, lines 57-67). As mentioned previously, since Applicants do not specify how high is the “high oxygen permeability”, Lally’s method reads on the limitation of the instant claim. The ophthalmic molding can be a contact lens, an intraocular lens, an eye bandage or an artificial cornea (col. 15, lines 50-53). Therefore, its surface should be an ophthalmically compatible surface.

With respect to Claims 5, 12-13 and 26, a comonomer of perfluoroalkyl (meth)acrylate, perfluoroalkylethylthiocarbonylaminoethyl (meth)acrylate, tris(trimethylsiloxysilyl)propyl methacrylate, etc. can be used (col. 10, line 59 to col. 11, line 8).

With respect to Claims 6-8, 15-16, an inorganic or an organic pigment can be used. The blue copper phthalocyanine pigment is most preferable (col. 8, lines 40-48).

With respect to Claims 17 and 25, the aforementioned water soluble polymer precursor can be a dispersing agent for the pigment (col. 9, lines 7-24).

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With respect to Claim 21, the pigment can be in an amount of from about 0.0001 to 0.05 wt% (col. 8, lines 49-67).

With respect to Claims 22, a contact lens can be obtained wherein the polymerization time of the polymer precursor can be about 14 seconds (Example 6).

With respect to Claims 27-28, although Lally teaches that the water soluble precursor is preferably used as the pigment dispersing agent (col. 9, lines 15-18), it does not exclude the possibility of using other material as a dispersing agent (col. 9, lines 9-11). Furthermore, it is noted that the instant claim does not exclude the possibility of the dispersing agent being the same material as component (i). Therefore, due to the presence of the aforementioned comonomer, after mixing the pigment is essentially considered dispersed in the comonomer too. As mentioned previously, the comonomer can be tris(trimethylsiloxysilyl)propyl methacrylate (TRIS). Lally's contact lens reads on the soft, tinted ophthalmic lens of the instant claim (which is a product claim, not a process claim) because the dispersing agent can be TRIS which is eventually incorporated into the final lens matrix (i.e., absence of the pigment dispersion) after polymerization or crosslinking.

Claim Rejections - 35 USC § 103

12. Claims 7-16 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Covington in view of Hendrickson (US 5 106 533).

Covington discloses a flexible silicone contact lens containing a pigment as described in paragraph 10, which incorporated herein by reference.

With respect to Claims 7-8, the difference between Covington and the present invention is the requirement of a phthalocyanine pigment, particularly a copper phthalocyanine blue.

Hendrickson teaches the use of ultrafine copper phthalocyanine particles to be used in contact lenses (col. 12, lines 21-53). The motivation of using the ultrafine copper phthalocyanine is to increase the color strength and decrease the diffuse scattering of the contact lenses (col. 12, line 53 to col. 13, line 5). In light of the benefit mentioned, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Hendrickson's ultrafine copper phthalocyanine particles into Covington's contact lens.

With respect to Claims 9-12, 14-16 and 23, Convinton further teaches a process of preparing the contact lens (col. 8, line 67 to col. 10, line 9). Note that Hendrickson teaches the use of the pigment in a dispersed form (col. 5, lines 29-45).

With respect to Claim 13, Convinton further teaches the use of a dimethylpolysiloxane macromer (col. 4, lines 65-68).

With respect to Claim 20, Hendrickson teaches the use of methyl methacrylate or HEMA as a dispersing agent (col. 8, lines 44-62).

With respect to Claim 21, Convinton further teaches the use of a pigment in an amount of 0.0001 to 0.01 parts by weight (col. 10, lines 10-22).

With respect to Claim 22, it is noted that when the polymerization is too long, degradation of the lens material might occur. In other words, the polymerization time is a result-effect variable. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a process with whatever polymerization time through routine experimentation in order to avoid the degradation of the lens material. Especially, Applicants do

not show the criticality of the polymerization time being less than about 5 minutes. See MPEP 2144.05 (II).

Response to Arguments

13. Applicant's arguments with respect to Claims 1-8, 23-25, 27 and 29-30 have been considered but are moot in view of the new ground(s) of rejection.

The instant claims are rejected as described above.

14. Claims 18-19 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

None of the references cited above teaches or fairly suggests a method for making a soft, tinted ophthalmic molding comprising a step of providing a pigment dispersion wherein the dispersing agent is a (meth)acrylated siloxane monomer or comprising an alkylene tris(trimethylsiloxy)silane.

15. The "X" reference, GB 2 039 932, cited in the international search report has been applied using its US equivalent (Covington, US 4 423 195).

16. The "X" reference, WO 94/03324 cited in the international search report is not relied upon because it does not teach or fairly suggest a particle pigment.

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17. In the information disclosure statement filed on February 24, 2003, the reference "AR" has been clarified as the international search report for PCT/EP 02/00020 as indicated in the hard copy provided by Applicants.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kuo-Liang Peng whose telephone number is (703) 306-5550. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Dawson, can be reached on (703) 308-2340. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9310.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

klp
July 25, 2003


Kuo-Liang Peng
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